



Medical Coverage Policy

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Plantar Fasciitis Treatments

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Overview

This Coverage Policy addresses various minimally invasive treatments for plantar fasciitis.

Coverage Policy

For information on the use of splints/foot orthoses associated with plantar fasciitis, refer to the Cigna Coverage Policy Orthotic Devices and Shoes.

Each of the following interventions is not covered or reimbursable for the treatment of plantar fasciitis:

- extracorporeal shock wave therapy (ESWT), including extracorporeal pulse activation therapy (EPAT®)
- laser therapy (low-level laser therapy/LLLT)
- pulsed radiofrequency electromagnetic field (PREF) therapy
- radiotherapy
- stem cell therapy
- stereotactic radiofrequency thermal lesioning

Each of the following interventions is considered experimental, investigational or unproven for the treatment of plantar fasciitis:

- amniotic-derived allografts (e.g., human amniotic membrane injections)
- autologous platelet-derived growth factors
- coblation® (e.g., Topaz™)
- electron-generating devices
- intracorporeal pneumatic shock therapy (IPST)
- low-load prolonged-duration stretch (LLPS) devices (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®)
- microwave diathermy
- percutaneous ultrasonic ablation (e.g., Tenex Health TX®)
- trigger-point needling and infiltration of the proximal medial gastrocnemius muscle

General Background

Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, a thick fibrous band which connects the heel to the toes. It is a common cause of heel pain in adults. Symptoms usually start gradually with mild pain at the heel, pain after exercise and pain with standing first thing in the morning. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. Risk factors for plantar fasciitis may include: obesity, age, being female, limited dorsiflexion of the ankle joint, prolonged weight bearing, and an increase in the amount of walking or running. Heel spurs are not necessarily associated with plantar fasciitis; heel

spurs may be found in asymptomatic patients. Race and ethnicity is not significant in the incidence of plantar fasciitis (Young, 2019). Early treatment generally results in a shorter duration of symptoms.

First-Line Treatment

The mainstay of nonsurgical treatment and the standard of care for initial treatment is a program of stretching exercises, ice, activity modification, weight loss in overweight patients, recommendations for appropriate footwear, arch taping, nonsteroidal anti-inflammatory medications and shock-absorbing shoe inserts or orthoses. Prefabricated orthoses have been shown to be adequate for the majority of patients with various heel pain syndromes.

Iontophoresis is also an accepted noninvasive therapy for plantar fasciitis. Iontophoresis is the use of electric impulses from a low-voltage galvanic current stimulation unit to drive topical corticosteroids into soft tissue structures. The effectiveness of iontophoresis combined with traditional modalities has been demonstrated in randomized controlled trials (RCTs) (Osborne and Allison, 2006; Gudeman, et al., 1997). Iontophoresis may be tried as part of a first-line physical therapy program.

Second-Line Treatment

In the event early treatment fails, night splints, steroidal anti-inflammatory injections or a walking cast are the next level of the standard of care.

A night dorsiflexion splint allows passive stretching of the calf and the plantar fascia during sleep. In theory, it also allows healing to occur while the plantar fascia is in an elongated position, thereby creating less tension with the first step in the morning. A night splint can be molded from plaster or fiberglass casting material or may be a prefabricated plastic brace. A number of studies support the efficacy of night splints (Roos, et al., 2006; Crawford and Thomson, 2003; Barry, et al., 2002; Berlet, et al., 2002).

Evidence on the effectiveness of steroid injections in reducing pain in patients with plantar fasciitis includes systematic reviews of randomized and quasi-randomized controlled trials (Whittaker, et al., 2019; David, et al., 2017; Crawford and Thomson, 2003). In general, the studies that compared steroid injections with placebo substances showed initial significant improvement; however, studies that included follow-up after one month showed no difference in outcome at that time. This suggests that the effectiveness of steroid injections is short-term. Risks of steroid injection into the heel include rupture of the plantar fascia and fat pad atrophy.

The use of a short-leg walking cast for several weeks is a standard of care as a final conservative step in the treatment of plantar fasciitis.

Surgical Intervention

Surgical intervention should be considered only for intractable pain which has not responded to 6–12 months of proper conservative treatment (Buchbinder, 2022). Plantar fasciotomy can be conducted using open or endoscopic techniques. Endoscopic plantar fasciotomy is a less invasive technique requiring an incision of less than one-half inch in length and utilizing an arthroscope to visualize and release the fascia. It has been proposed as an improvement over open plantar fasciotomy, resulting in less trauma and improved recovery times. There are a substantial number of retrospective studies supporting the use of endoscopic plantar fasciotomy. Based on the large number of reports of relief of heel pain from a series of nonrandomized trials, endoscopic plantar fasciotomy appears effective in the treatment of plantar fasciitis (Urovitz, et al., 2008, Boyle and Slater, 2003).

Unproven Therapies for Plantar Fasciitis

There are many therapies that have been suggested for treatment of plantar fasciitis that are not proven in the literature and not accepted as standard of care.

Amniotic-Derived Allografts: Amniotic-derived allografts are harvested from human placenta tissue soon after birth and processed into injectable solutions that are hypothesized to reduce inflammation and enhance healing when injected into soft tissue such as the plantar fascia.

U.S. Food and Drug Administration (FDA): Amniotic membrane is a banked human tissue regulated by the American Association of Tissue Banks® (AATB) and does not require FDA approval. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of human cell, tissue, and cellular and tissue-based products (HCT/Ps) (FDA, 2022).

Literature Review Amniotic-Derived Allografts: A Hayes Technology Assessment (2019) reviewed the available evidence on human amniotic membrane (HAM) injections for treatment of chronic plantar fasciitis (n=4 studies; n=23–47 patients). The evidence consisted of three randomized controlled trials (RCTs) that compared allograft treatment to saline-placebo control (two studies) or corticosteroid injection (one study). An additional prospective, open-label pretest/posttest study compared baseline pain assessments with follow-up assessments. Outcome measures included: pain relief, functional improvement and quality of life. Follow-ups ranged from eight to 12 weeks. Comparatively, corticosteroid injections were favored over HAM injections in some function and pain assessments. All other assessments demonstrated no statistically significant differences between HAM injections and corticosteroids. When compared to saline controls, HAM injections were favored in measures of function (two studies), pain (two studies), and quality of life (one study). The results from a single-arm pretest/posttest study suggest that HAM injections resulted in a statistically significant improvement in pain compared with baseline scores. In the eligible studies, HAM injections were well tolerated with minimal side effects, there were no deaths, and no treatment-related serious adverse events as reported in three studies. Author noted limitations included small sample sizes, lack of an active comparator (three studies), lack of double-blinding (three studies), and limited follow-up (12 weeks or less). Larger, double-blind RCTs with active treatment comparators (injectables, surgery, extracorporeal shockwave therapy) are needed to fully evaluate the effectiveness and safety of amniotic tissue-derived allograft treatments for PF.

Cazzell et al. (2018) conducted a multicenter, randomized controlled trial (n=145) to investigate the safety and effectiveness of a micronized dehydrated human amnion/chorion membrane (dHACM) injection (Amniofix) for the treatment of plantar fasciitis (PF). Inclusion criteria were: age 21 to < 80 years; confirmed diagnosis of PF for 1–18 months; VAS pain score of ≥ 45 at time of randomization; and had undergone conservative treatment for ≥ 30 days (rest, ice, compression, and elevation [RICE]; stretching exercises; nonsteroidal anti-inflammatory drugs [NSAIDs] and/or orthotics). Patients were excluded if they had trauma or previous surgery to the affected area; bilateral PF; prior use of lower limb injection therapy; diabetes and multiple other comorbidities and contraindications. Patients were randomized to receive one injection of Amniofix (n=73) or sodium chloride placebo (n=72). The primary outcome was the mean change in the visual analog scale (VAS) score between baseline and three months post-injection. Secondary outcome was mean change in Foot Function Index–Revised (FFI-R) score between baseline and three months follow-up. Overall, at the three month follow-up, 60 subjects in the treatment group compared to 34 control subjects reported at least a 50% reduction in VAS scores from baseline. VAS scores in the treatment group were 76% lower compared with a 45% reduction in mean VAS scores for controls ($p < 0.0001$). Compared to baseline the FFI-R scores for treatment subjects showed a significant mean reduction ($p = 0.0004$) of 60% compared to a 40% reduction in the control group at the three month follow-up. Control group subjects reported a reduction in pain and improved function over time. No serious adverse events were related to the study. Two cases

of post-injection pain at the injection site and one case of post-injection itching were considered normal events. Limitations of the study include the small patient population and short-term follow-up. It is unknown if additional injections would be effective for persistent symptoms. Three Amniofix and two control subjects did not complete the three month follow-up and the last observation data was carried forward to the three-month analysis.

Hanselman et al. (2015) conducted a randomized, controlled, double-blind, single-center pilot study that compared cryopreserved human amniotic membrane (c-hAM) to corticosteroid injection. Patients (n=24) were randomized into one of two treatment groups: c-hAM injection (n=9) using AM3 (now known as Clarix®) or corticosteroid injection (n=14) using Depo Medrol. The groups received an injection of c-hAM or corticosteroid injection at their initial baseline visit with an option for a second injection at their first six week follow-up. Adults aged 18–65 years with plantar fasciitis were included if symptoms were present for a minimum of three months but less than one year, and without coexisting foot or ankle pathology. The primary outcome was the measurement of foot health and impact on quality of life using the Foot Health Status Questionnaire (FHSQ). The secondary outcomes measured were pain using the Visual Analog Scale (VAS) and verbally reported percentage improvement. Follow-up was obtained 12 weeks after the most recent injection. A total of 96% of the patients completed the required 12 weeks of follow-up and were included in the analysis. One subject was lost to follow-up. Three patients in each group received second injections. In the one injection group, shoe fit at six weeks (p=0.0244) and general health at six weeks (p=0.0132) were statistically greater in the corticosteroid group. In the two injection group, foot pain score at 18 weeks (p=0.0113) was statistically greater in the c-hAM group, indicating an improvement in foot pain. All other variables resulted in no significant difference. Verbal percentage improvement at 12 weeks (p=0.041) was statistically greater in the one injection steroid group. There were no adverse side effects experienced. Author noted limitations included: small patient population, short term follow-up, drug formulation was changed during the study and the risk of bias as patients were recruited through community and institutional advertising. The authors concluded that cryopreserved hAM injection may be safe and comparable to corticosteroid injection for treatment of plantar fasciitis. The authors stated that this is a pilot study and further investigation is required.

There is insufficient evidence in the published peer-reviewed medical literature to support the use of amniotic-derived allograft for the treatment of plantar fasciitis.

Autologous Platelet-Derived Growth Factors: Autologous platelet-derived growth factors (APDGF) also referred to as autologous platelet concentrate, platelet-rich plasma (PRP), platelet-rich concentrate, have been proposed for the treatment of multiple conditions to enhance healing. In addition to hard and soft tissue wound healing, purported benefits of this treatment include reduced inflammation, decreased blood loss, and reduced postoperative narcotic requirements. Several centrifuges are designed to concentrate platelet-enriched plasma from small amounts of autologous blood at the point of care. The platelet concentrate can then combine with other substances to form a gel for patient application. Outcomes have been documented using APDGF injection for a wide range of indications, including musculoskeletal conditions. APDGF injection has been evaluated as a treatment for plantar fasciitis in few randomized controlled trials (RCTs) showing no significant improvement when compared to a control group.

U.S. Food and Drug Administration (FDA): The Center for Biologics Evaluation and Research (CBER) regulates the collection of blood and blood components used for transfusion. The systems used for preparing autologous platelet-derived growth factors are FDA approved under the 510(k) process. In general, the systems are approved to be used at the patient's point of care and/or in a clinical laboratory to prepare autologous platelet-rich plasma/platelet concentrate from the patient's own blood (FDA, 2022a).

Literature Review Autologous Platelet-Derived Growth Factors: Atzmon et al. (2022) conducted a randomized, prospective trial that compared the efficacy of platelet-rich plasma (PRP) to partial plantar fasciotomy (PPF) surgery in patients with chronic plantar fasciitis (CPF). Patients diagnosed with recurrent CPF following conservative treatment for at least three months prior to treatment were included in the study. Patients (n=32) were randomly divided into two groups, a PRP treatment group (n=16), and a PPF group (n=16). Outcomes assessed pain and the limitations of activity using the Roles-Maudsley Scale (RM) and the Visual Analog Score (VAS). The outcomes were assessed during the preoperative visit and three, six, and 12 months postoperatively. All patients in both groups received the same post-treatment protocol, except for heel-raising insoles that were not allowed in the plantar fasciotomy group. Both procedures showed a reduction in RM scores during the follow-up year (9 to 1.62 for PPF and 8.7 to 2.4 for PRP). However, patients in the PPF group had significantly lower Roles-Maudsley Scale (RM) scores compared to the PRP group one-year after treatment ($p < 0.0001$). In addition, there was a significant difference in terms of change from preoperative to postoperative RM score, favoring the PRP group ($p < 0.0001$). There was no significant change in VAS pain between the two groups ($p = 0.366$). Author noted limitations included the small patient population and short term follow-up. No health disparities were identified by the investigators.

Vellingiri et al. (2022) conducted a prospective study assessed the efficacy, safety, side effects and complications of a local injection of platelet-rich plasma (PRP) compared to a corticosteroid (CS) injection (methylprednisolone) in the treatment of plantar fasciitis. Adults (n=110) who were diagnosed with plantar fasciitis for more than three months' duration and had failed conservative management methods, had Visual Analog Scale (VAS) pain was more than six and the patients with plantar fascia thickness > 5 mm when assessed by ultrasound were included in the study. Patients were assigned into two groups, PRP injection (n=55) and CS (n=55) methylprednisolone injection. Following the administration of injections, the patients' clinical, radiological, subjective and functional outcomes were assessed at the first, third and sixth month by using the Visual Analog Scale (VAS), Foot and Ankle Outcome Instrument Core Scale (FAI), Roles and Maudsley Scores (RMS), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hind foot scale and ultrasound of plantar fascia thickness. Ten patients were lost to follow-up and two patients had post-operative complications (superficial infection) in the PRP injection group, while ten patients had post-procedure complications (five patients developed superficial infections, three patients developed skin depigmentation, and two patients had atrophy of fat pad) in the corticosteroid injections (CSI) group. Infections subsided in all the patients as observed during subsequent follow-up. In the PRP injection group there was significant improvement at the first, third and sixth month in the VAS, AOFAS score and the measurement of the plantar fascia thickness (all $p < 0.001$). The FAI score was statistically significant between groups, in favor of the PRP group in the third and sixth month ($p < 0.001$). The rating of the Roles and Maudsley score was not measured for statistical significance, however the results were better in the PRP group compared to the CS group at three and six months. The study reported that significant improvement was seen in the PRP injection group when compared with the CSI group, although steroid injections show significant improvement in clinical, subjective rating, functional and radiological outcomes one month after injection. However, PRP injection gives better results in clinical, subjective rating, functional and radiological outcomes during six months when compared to the corticosteroid group. The author acknowledged study limitations included the small patient population, short-term follow-up and lack of a control group. An additional study limitation is that the population only included patients in India and the results may not be applicable to other races or ethnic group. In conclusion, the authors stated that in order to provide a clearer insight into the effectiveness of both treatment types, a randomized controlled trial with a larger population, a longer follow-up, and a control group is needed.

Kandil et al. (2020) conducted a prospective, single-blinded, randomized controlled trial (RCT) that evaluated the efficacy and safety of allogeneic growth factors (GF) injection compared to

placebo in patients with plantar fasciitis. Patients (n=150) were included in the study if they were age ≥ 20 years with plantar fasciitis. The patients were randomly placed into two groups: a treatment group (n=75) where each patient received a single local injection of allogeneic GFs, and a control group (n=75) where each patient received a single local injection of normal saline 0.9% as a placebo. All the patients were assessed for pain using visual analog scale (VAS) and functional improvement using the Foot Function Index–Revised short form (FFI-Rs) preinjection and at one, three, six, and 12 months postinjection. The primary and secondary outcomes measured the change the VAS score and the FFI-Rs between preinjection and at the three month follow-up, respectively. Additionally, patients were questioned about their satisfaction and adverse effects were recorded. At baseline, there was no statistically significant difference between the two groups regarding the mean VAS score ($p=0.45$) and the mean FFI-Rs score ($p=0.79$). At the three month follow-up, there was a significant reduction in the mean VAS score between the groups, in favor of the treatment group ($p<0.001$). At the 6- and 12-month follow-ups, the mean VAS score was 1.3 and 1.4 in the treatment group and 3.8 and 3.6 in the control group, respectively. At the three month follow-up, there was a significant reduction in mean FFI-Rs score in the treatment group compared to the control group ($p<0.001$). At the 6- and 12-month follow-ups, the mean FFI-Rs score was 21.4 and 21.7 in the treatment group and 33.5 and 32.6 in the control group, respectively. The patients' satisfaction was 92% (either completely or with reservations) in the treatment group, and 78.2% in the control group. Five patients in the treatment group experienced mild postinjection pain, which resolved within 2–4 days. No other adverse effects related to the procedure were reported. Author noted limitations included the lack of comparator group receiving an additional therapy, ultrasonography was not done to guide injections or assess the thickness of the plantar fascia before and after the procedure and a single injection was given to the patients and it is unknown if repeated injections are beneficial. Additional limitations include the short term follow-up, small patient population and population studied only included Egyptians and the results may not be applicable to other races or ethnic groups. The authors concluded that allogeneic GFs injection in patients with plantar fasciitis is effective and safe. However, additional studies are needed to evaluate their adverse effects, immunogenicity, and microbiological safety.

Khurana et al. (2020) conducted a randomized control trial that compared the effectiveness of PRP and methylprednisone when injected in patients with plantar fasciitis who had failed conservative management. Adults (n=118) diagnosed with plantar fasciitis and refractory pain following four weeks of conservative treatment were enrolled in the study. Patients were randomized into two groups: Group A (n=58) received an injection of platelet rich plasma (PRP), and Group B (n=60) received an injection of corticosteroid. All patients underwent conventional radiographs and magnetic resonance imaging (MRI) of the involved foot to rule out stress fractures, associated bone lesions or other causes of plantar heel pain. Patients were assessed for pain on the day of presentation and then after therapy at two weeks, four weeks, three months, and six months using the Visual Analog Scale, and AOFAS hind-foot Score was taken at the six month follow-up. Both groups experienced a significant improvement of VAS ($p<0.001$). The maximum change from the pre-injection value was observed at the 6 months. There was a significant difference between the groups in terms of AOFAS Score at six months ($p<0.001$), with the mean AOFAS Score being higher in the PRP group. The limitations of the study included the unblinded study design, small patient population and short-term follow-up. Additionally, the present study may be underpowered as the drop-out rate was greater than the initial allowance of 15%. No health disparities were identified by the investigators.

Tabrizi et al. (2020) conducted a single-blind, randomized controlled trial that investigated the efficacy of platelet-rich plasma (PRP) injection compared to local corticosteroid injection in obese patients with chronic plantar heel pain (CPHP). Obese patients (n=32) with chronic plantar heel pain were randomly allocated to two groups; group 1 (n=16) received an injection of 40mg dimethylprednisolone into the painful heel, whereas group 2 (n=16) received three separate injections of PRP, with each injection administered one week apart. Patients with obesity (BMI \geq

30 kg/m²) and failure of conservative treatment for a minimum of two months were eligible for inclusion in study. The outcomes measured pain severity response using the VAS scale and patient function using the Foot Function Index (FFI). Morning and daily pain of the patients was recorded before the injection, and the pain severities of the patients were evaluated at eight, 12, and 24 weeks after treatment. Symptom return and recurrence were determined within six months of follow-up. The groups were compared at baseline and at 24 weeks after the injection, or course of injections, was administered. One patient was lost to follow-up, therefore, 31 (96.9%) of those treated were included in the analyses. In the corticosteroid-treated group, 11 patients received bilateral injection. In the PRP treated group, nine patients received bilateral injection. There was no significant differences in morning and total pain severities or FFI between the groups at baseline. At 24 weeks following treatment, final pain and morning pain scores along with mean foot function index scores were statistically significant in patients treated with corticosteroid compared to those treated with PRP ($p < 0.001$ and $p < 0.001$, respectively). Author noted limitations included: treatments were likely influenced by concomitant use of oral NSAID medication and other adjunct therapies, plantar calcaneal spurs were not identified, not all patients had bilateral heel pain, and three weekly injections of PRP were done compared with one injection of corticosteroid. The authors concluded that pain reduction and functional improvement were better in the corticosteroid-treated group compared to the PRP-treated group at six months after the course of injection therapy.

Keene et al. (2019) conducted a placebo controlled, multi-center, two arm, parallel group, superiority randomized controlled trial (PATH-2) to determine the clinical efficacy of platelet rich plasma in treating acute, non-surgically managed rupture of the Achilles tendon. Patients were included in the study if they were age ≥ 18 years; had a clinical diagnosis of a complete acute mid-substance rupture of the Achilles tendon; were within 12 days of injury; were able to walk unaided pre-injury; and were being managed non-surgically by immobilizing the ankle in a cast, splint, or boot. Patients ($n=230$) were randomized 1:1 to platelet rich plasma ($n=114$) or placebo (dry needle; $n=116$) injection. All participants received standard rehabilitation care (ankle immobilization followed by physiotherapy). Primary outcome measured muscle tendon function at 24 weeks using the validated heel rise endurance test. Secondary outcomes were measured at four, seven, 13 and 24 weeks and included patient reported function (Achilles tendon rupture score), quality of life (short form 12 version 2[®]), pain (visual analogue scale), goal attainment (patient specific functional scale), and adverse events. At 24 weeks, 202 (88%) participants completed the heel rise endurance test and 216 (94%) of the patient reported outcomes. No difference was detected in muscle tendon function between participants receiving platelet rich plasma injections and those receiving placebo injections or in any secondary outcomes or adverse event rates. Author noted limitations included different volumes of whole blood were taken from the two randomization groups (55 mL platelet rich plasma/5 mL placebo) and participant masking could have been compromised. The authors concluded that there is no evidence that platelet rich plasma when compared to placebo can improve objective muscle tendon function, patient reported function, or quality of life after acute Achilles tendon rupture.

Peerbooms et al (2019) conducted a randomized controlled trial to determine the effectiveness of PRP compared to corticosteroid injections for chronic plantar fasciitis. Patients ($n=115$) with chronic plantar fasciitis were allocated to have a steroid injection ($n=52$) or PRP ($n=63$). Included patients were age 18 years and older with plantar fasciitis (at least six months' duration) and failed nonoperative treatment. Patients were able to understand the informed consent with the morning Foot Function Index (FFI) Pain score at 5 (0-10 scale). The primary outcome measure was the Foot Function Index (FFI) pain score. Secondary outcome measures were function scored by the FFI Activity, FFI Disability and American Orthopaedic Foot & Ankle Society, along with quality of life, as scored with the short version of the World Health Organization Quality of Life (WHOQOL-BREF). All outcomes were measured at baseline and at four, 12, and 26 weeks and one year after the procedure. Thirty-Three patients were lost to follow-up, and the outcomes were

reported on the patients (n=82) that completed the study (n=46/PRP group; n=36/corticosteroid group). In the corticosteroid group, FFI Pain scores decreased quickly and then remained stable during follow-up. In the PRP group, FFI Pain reduction was more modest but reached a lower point after 12 months than the control group. After adjusting for baseline differences, the PRP group showed significantly lower pain and disability scores at the one year follow-up than the control group (p=0.012 and p=0.016, respectively). The number of patients with at least 25% improvement (FFI Pain score) between baseline and 12-month follow-up differed significantly between the groups. Of the 46 patients in the PRP group, 39 (84.4%) improved at least 25%, while 20 (55.6%) of the 36 in the corticosteroid group showed such an improvement (p=0.003). Author noted limitations included a violation of protocol, 16 patients were treated with a 30mL PRP kit instead of the 60mL PRP kit as described in the protocol. Second, ultrasound-guided injections were not used for both groups. A final limitation is the lack of data on the characteristics between the study group and the eight patients who were not suitable for further allocation, potentially leading to bias. The authors concluded that treatment of patients with chronic plantar fasciitis with PRP seems to reduce pain and increase function more as compared with the effect of corticosteroid injection. However, future decisions for the application of PRP for PF should be confirmed by further follow-up from this study.

Shetty et al. (2019) conducted a three-arm randomized controlled trial that compared platelet rich plasma (PRP) with corticosteroid (CS) and placebo for the treatment of chronic plantar fasciitis with regard to pain and function. Patients (n=90) were blindly randomized into three groups, PRP (n=30), CS (n=30), and placebo (n=30). Patients were included in the study if they were age \geq 18 years with a diagnosis of chronic plantar fasciitis who had failed conservative treatment for \leq 3 months. The PRP group received 2 mL of PRP mixed with 1 mL of 1% lidocaine; the CS group received 2 mL of methylprednisolone acetate (40 mg/mL) mixed with 1 mL of 1% lidocaine; and the placebo group received 2 mL of 0.9% normal saline mixed with 1mL of 1% lidocaine. The outcomes measured pain, function and general health. All patients were followed at one week, three weeks, and three, six, 12, and 18 months using a self-developed item set for demographic data and validated tools to assess pain (visual analog scale [VAS]), function (Roles and Maudsley [R&M] score) and general health (Short Form 12 Health Survey [SF-12]). All patients completed their follow-up visits. All groups had significant improvement in VAS scores, the R&M score and the SF-12 score between preinjection and the 18-month follow-up. The corticosteroid group demonstrated the greatest improvement in VAS scores and the R&M score during the first three weeks. The PRP group demonstrated significant improvement in the VAS scores (p=0.05/six months; p=0.01/12 months; p=0.005/18 months) and the R&M score (p=0.05/12 months; p=0.05/18 months) during the 3–18-month follow-up period. Clinical significance was not reached for the SF-12 score in the 3–18-month follow-up period. No patients suffered any complication (local or systemic). The author noted limitations were the self-bias of measuring own results and the institutional bias of producing PRP.

Soraganvi et al. (2019) conducted a double-blind, randomized controlled trial that compared the efficacy of PRP and steroid injection in the treatment of chronic plantar fasciitis and analyzed the effect on the thickened plantar fascia. Patients with a clinical diagnosis of chronic plantar fasciitis after failed conservative treatment and plantar fascia thickness more than 4mm were included in the study. Patients (n=60) were randomized into two groups, Group A (n=30) received a PRP (3ml) injection and Group B (n=30) received a steroid injection (Depomedrol 80mg (2ml) + 0.5ml xylocaine 2%). All patients in both groups were advised on plantar fascia stretching exercise. The outcomes measured pain and function using the visual analog scale (VAS) and the American Orthopedic Foot and Ankle Society (AOFAS) score. Assessment was done before injection, at six weeks, three months and six months follow-up after injection. Plantar fascia thickness was assessed before the intervention and six months after treatment using sonography. Three patients were lost to follow-up and the results were analyzed using 57 patients. The mean VAS score in Group A was statistically significant when compared to Group B at six weeks, three months and

six months ($p < 0.007$, $p < 0.001$ and $p < 0.001$, respectively). At six months, the AOFAS score and the reduction in the thickness of plantar fascia were clinically significant in group A compared to Group B ($p < 0.001$, $p < 0.0003$, respectively). An author noted limitation was the variability of platelet concentration due to the lack of standardization in preparation, concentration and dosage of platelets. The authors concluded that local injection of platelet-rich plasma is an effective treatment option for chronic plantar fasciitis when compared with steroid injection with long lasting beneficial effect. However, further basic research is necessary for understanding the exact mechanism of action of PRP.

Jain et al. (2018) conducted a prospective randomized that compared the efficacy of corticosteroids and platelet rich plasma (PRP) in the treatment of plantar fasciitis. Patients ($n=80$) were randomly allocated into two groups of 40 each (group A and group B). Patients were treated with local corticosteroid injection in group A and autologous PRP injection in group B. Included patients were diagnosed with plantar fasciitis with failure of conservative treatment (stretching exercises, nonsteroidal anti-inflammatory drugs, and heel pads) for at least three months, a pain level higher than five on the visual analog scale and the ability to understand the informed consent. Primary outcomes included pain scores using the visual analog scale (VAS), subjective evaluation of the outcome of the procedure (modified Roles and Maudsley score), functional outcomes (FAI core scale and AOFAS ankle-hindfoot score) and the thickness of the plantar fascia using ultrasonography. They were assessed at baseline with follow-ups occurring after the injection at one month, three months, and six months. Post-injection, there was significant improvement in pain, patient evaluation of the procedure outcome and functional outcomes in both groups. The thickness of the plantar fascia post-injection reduced significantly in the steroid group as compared to the PRP group at the one month and three month follow-up ($p=0.004$ and $p=0.011$, respectively). At the six month follow-up the difference in thickness between the two groups became statistically insignificant ($p=0.148$). There were no reported complications from PRP or corticosteroid injections. Author noted limitations included small patient population, short term follow-up, unblinding and the lack of a control group. The authors concluded that the treatment of plantar fasciitis with steroid or PRP injection was equally effective.

Hayes conducted a comparative effectiveness review on PRP for the treatment of Achilles tendon rupture (ATR) and plantar fasciitis. The review included 13 randomized controlled trials: three studies for the treatment of ATR, two studies using PRP during ATR surgery, and eight studies for the treatment of plantar fasciitis. Comparators included: no PRP; conventional treatment; corticosteroids (CS); endoscopic plantar fasciotomy (EPF); extracorporeal shockwave therapy (ESWT); high-volume injection of saline between the tendon and the tendon sheath (HVI); low dose radiation (LDR); saline; and stromal vascular fraction (SVF). Follow-ups ranged from 16 weeks to 42 months. The use of PRP during surgical treatment of ATR did not yield better functional outcomes compared to surgery without PRP. The evidence for use of PRP in AT was limited and did not support PRP over saline. Regarding PRP for the treatment of plantar fasciitis (PF), three randomized controlled trials suggested that PRP was associated with better functional improvement and pain relief at 6–24 months compared with CS. However, differences between PRP and CS were not found in another study with shorter follow-ups. Data for PRP compared with other PF treatments (i.e., conventional treatment, ESWT, EPF, or LDR) were limited and reported no significant differences in functional or pain outcomes. No serious PRP adverse events were reported. Overall, the quality of the evidence was low due to the limited number of studies and lack of comparison to established treatment modalities. There is insufficient evidence to establish patient selection criteria for the use of PRP in the treatment of conditions of the Achilles tendon and plantar fascia. The 2020 review revealed nineteen abstracts, including eight randomized controlled trials, 10 systematic reviews with meta-analyses, and one systematic review. The studies did not change Hayes original conclusion (Hayes, 2018).

Yang et al. (2017) performed a meta-analysis (n=9 RCTs/430 patients) to evaluate the current evidence concerning the safety and efficacy of PRP as a treatment for plantar fasciitis compared to steroid treatments. RCTs or prospective cohort studies that compared PRP to a control (e.g., steroid treatment) in patients diagnosed with plantar fasciitis were included. Studies were excluded in which subjects had a traumatic disease, a history of surgical interventions, or systemic disorders such as rheumatoid arthritis. Outcome measurements included the visual analogue scale (VAS), the Foot and Ankle Disability Index (FADI), American Orthopedic Foot and Ankle Society (AOFAS) scale, and the Roles and Maudsley Score (RMS). Follow-up times were divided into short periods (two–four weeks), intermediate periods (four–24 weeks), and long periods (≥ 24 weeks through 48 weeks). No significant differences in the VAS scores were observed between the two groups in the short term and intermediate term, however, PRP demonstrated better long-term efficacy than steroid treatments ($p=0.03$). No significant differences in the FADI and AOFAS Scale were observed between the groups after 12 weeks. Similarly no significant differences in the RMS were between groups was found after six months. Limitations of this meta-analysis include small sample size and heterogeneity between studies. Additional well-designed, long term studies are needed to establish the role of PRP as a treatment for plantar fasciitis.

Monto (2014) published results of a single-blinded, prospective, randomized, longitudinal study (n=40) of patients with chronic plantar fasciitis to compare the effectiveness of autologous PRP and corticosteroid injection. Chronic refractory plantar fasciitis was defined as those patients who had experienced at least four months of heel pain despite a standardized trial of conservative treatment including rest, physical therapy. Group one received a single ultrasound-guided injection of cortisone, and group two was treated with a single ultrasound-guided injection of autologous PRP. Follow-up occurred through 24 months following injection treatment. The difference between the post-treatment pain scoring results of the cortisone and PRP groups was clinically significant in favor of PRP ($p=0.001$) at all follow-up evaluations. An acknowledged primary limitation of this study is the single-blinded design. Study results suggest that PRP may provide improved pain control compared to cortisone injection. However larger well-designed, controlled studies are needed to validate this finding.

A comparative study (n=60) by Akşahin et al. (2012) evaluated patients with chronic plantar fasciitis treated with corticosteroid injection versus platelet rich plasma injection. Satisfactory results were achieved with both treatment methods. There were no significant differences in pain scores at three weeks and six months following injections ($p>0.05$). Study limitations include small patient population, short-term follow-up, and lack of randomized design.

de Vos et al. (2010) conducted a systematic review (n=11 studies) of the evidence on autologous growth factor injections of whole blood or platelet-rich plasma for chronic tendinopathy. Chronic tendinopathy in this study included wrist extensors, flexors, plantar fasciopathy and patellar tendinopathy. There were six observational, non-controlled studies and five controlled clinical trials, two of which were determined to have appropriate randomization. The mean number of subjects was 40, with a range 20–100. Patients with chronic plantar fasciopathy were treated in three studies (n=218 subjects). Outcome measures included measurements of pain and function. The review found strong evidence that the use of injections with autologous whole blood should not be recommended. No high-quality studies were found on platelet-rich plasma treatment.

There is insufficient evidence in the published peer-reviewed medical literature to support the use of autologous blood injection for the treatment of plantar fasciitis.

Coblation®: Coblation, also referred to as cold or controlled ablation, has been proposed as a therapy for plantar fasciitis. Coblation bipolar technology uses radiofrequency energy to excite the electrolytes in a conductive medium, such as saline solution, creating precisely focused plasma. The plasma particles are then able to break molecular bonds within tissue, causing the tissue to

dissolve at relatively low temperatures. It is theorized that this plasma radiofrequency-based microsurgery may promote an angiogenic healing response. Because the current does not pass directly through tissue, there is minimal thermal injury to any surrounding tissues.

U.S. Food and Drug Administration (FDA): Coblation technology can be delivered via a number of different wands, hand pieces and other electrosurgical systems. The ArthroCare Topaz™ MicroDebrider™ (ArthroCare Corporation, Sunnyvale, CA) was granted marketing approval by the FDA via the 510(k) process on March 5, 2006, because it is considered to be substantially equivalent to another device already on the market. The 510(k) summary stated that the orthopedic system is substantially equivalent to the ArthroCare Topaz™ ArthroWands. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the Topaz Microdebrider prior to marketing the device. According to the FDA, the Topaz MicroDebrider is indicated for debridement, resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic and arthroscopic procedures (FDA, 2016).

Literature Review Coblation: Studies in the published peer-reviewed literature assessing the effectiveness of coblation-based fasciotomy for relieving pain associated with plantar fasciitis are lacking. Therefore, coblation technology for this indication is unproven at present.

Electron-Generating Devices: There is no evidence to support the use of electron generating devices in the treatment of plantar fasciitis (Crawford and Thomson, 2003).

Extracorporeal Shock Wave Therapy (ESWT): ESWT, also called orthotripsy, is a noninvasive treatment that involves delivery of 1000–3000 shock waves to the painful heel region and has been introduced as an alternative to surgery for patients with chronic plantar fasciitis that has not responded to medical therapy.

The two types of ESWT are focused and radial. Focused ESWT directs shock waves at a targeted area with high tissue penetration where it is proposed to stimulate healing and disrupts pain signals. The shock waves may be generated using electrohydraulic, electromagnetic or piezoelectric technology (Hayes, 2016a). The difference between the three methods of generation is the time at which the shockwave forms (Roerdink, et al., 2017).

Radial ESWT uses pneumatic (compressed air) devices to deliver radial shock waves to a wider area than focused ESWT at a relatively low energy level (Hayes, 2016b). This generates stress waves in the applicator that transmit pressure waves (radial shock waves) non-invasively into tissue. Since the waves generated by radial ESWT are not true shock waves, the technology is also referred to as radial pressure wave therapy or extracorporeal pulse activation therapy (EPAT) (Császár, et al., 2015). However, published literature continues to refer to radially generated wave therapy as radial ESWT.

U.S. Food and Drug Administration (FDA): A number of ESWT devices for the treatment of plantar fasciitis are currently approved by the U.S. FDA including the OssaTron® lithotripter (HealthTronics, Marietta, GA); the Epos™ Ultra high-energy device (Dornier Medical Systems, Germering, Germany); the Orthospec™ (Medispec, Ltd, Germantown, MD); the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY); and the EMS Swiss Dolorclast® (Electro Medical Systems [EMS], North Attleboro, MA).

Literature Review ESWT: The safety and effectiveness of ESWT for the treatment of plantar fasciitis have been evaluated in technology assessments, meta-analyses, and randomized controlled trials (RCTs). A number of RCTs (n=45–272) have compared ESWT to placebo, conservative treatment or steroid injections for the treatment of plantar fasciitis with conflicting results. In some studies, there is a greater reduction in heel pain in patients treated with ESWT

compared to placebo (Ibrahim, et al., 2017; Gollwitzer, et al., 2015; Othman and Ragab, 2010; Ibrahim, et al., 2010; Gerdesmeyer, et al., 2008), while similar improvement rates for both treatment and placebo groups have been reported in other studies (Radwan, et al., 2012). An RCT (40) by Eslamian et al. (2016) compared radial ESWT (n=20) to a single steroid injection (n=20) for plantar fasciitis and found that both interventions caused improvement in pain and functional ability two months after treatment. Inter-group differences were not significant ($p=0.072$); however the foot function index was improved more with ESWT, and patients were more satisfied with ESWT. An RCT (n=32) by Greve et al. (2009) compared radial shockwave treatment (n=16) and conventional physiotherapy (n=16) for plantar fasciitis and found ESWT to be no more effective than conventional physiotherapy three months after treatment. An RCT (n=149) by Wang et al. (2007) found that patients who received ESWT showed significantly better pain and function scores compared to those who received conservative treatment ($p<0.001$). In general, these studies have limitations such as small sample sizes and short-term follow-up that limit the generalizability of their results.

Cinar et al. (2020) conducted a randomized controlled trial (RCT) that evaluated if extracorporeal shockwave therapy (ESWT) combined with usual care (exercise and orthotic support) was comparable to usual care in improving foot function and walking velocity in patient with plantar fasciitis. Patients with plantar fasciitis pain persisting for at least one month with a minimum score of 5 on the 10-point visual analog scale (VAS); pain felt in the morning at first step over the plantar fascia in the last week before enrolling the study; tenderness to palpation over medial calcaneal tuberosity or along plantar fascia; ≥ 18 years; and agreement to participate and complete treatment and follow-up assessments (without participating in any other therapies including anti-inflammatory drugs and corticosteroid medication) were randomly allocated into two groups: ESWT (n =23), and control (n =21). Both groups were instructed to wear full-length silicone insole for three months and to practice home exercise for three weeks. Patients in the ESWT group were also treated with a radial ESWT device once a week for three weeks. The primary outcome of this study measured functional ability using the function subscale of American orthopedic foot and ankle society (AOFAS-F) score and 12 minutes walking test including walking speed and cadence. Assessments were performed at baseline, after completion of the three week courses of treatment and at the 12-week follow-up assessment. Results showed that there was a significant improvement in AOFAS-F total score and walking speed over three months in both groups ($p<0.001$, $p=0.04$ respectively). Groups were comparable with each other for both walking speed and AOFAS-F at all follow-up assessments ($p>0.05$). Author noted limitations included the small patient population, short term follow-up and the lack of a non-treatment group. Additionally, patients were in the acute phase of plantar fasciitis and the treatment effect of ESWT might not be as efficient as when in chronic condition. The authors concluded that ESWT did not have an additive benefit over usual care to improve foot function and walking performance in patient with plantar fasciitis over three months post-treatment. Future studies are needed to investigate the benefits of providing adjunctive electrotherapeutic modalities over exercises including different gait related outcomes using high quality measures.

Gezginaslan, et al. (2021) compared the effectiveness of density and number of sessions of extracorporeal shock wave therapy (ESWT) in plantar fasciitis (PF) patients in a double-blind, prospective, randomized-controlled study. A total of 94 patients with the diagnosis of PF were included in the study. All patients were randomly divided into three groups. Group 1 (n = 33) received a total of seven sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm^2); Group 2 (n = 31) received a total of three sessions of H-ESWT (0.26 mJ/mm^2); Group 3 (n = 30) received total of seven sessions of low-energy flux density ($< 0.08 \text{ mJ/mm}^2$) with three days interval. At baseline and one month after the treatment, the Visual Analog Scale (VAS), Short Form-36, Foot Function Index (FFI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, and Six-Minute Walking Test (6MWT) scores were compared among the groups. Of the patients, 69 were females and 25 were males with a mean age of 45.0 ± 8.43 (range, 25-67) years. There

were no statistical differences in the age, sex, demographic characteristics, and baseline VAS, FFI, 6MWT, and FACIT scores between the groups ($p > 0.05$). However, there was a statistical decrease in the VAS, FACIT, and FFI scores in all groups after treatment compared to baseline, although only the 6MWT, and Short Form-36 subscale scores were statistically higher ($p < 0.05$). There was also a statistical difference in the scale scores in Group 1 versus Group 2; and in Group 2 versus Group 3. Per the authors, the study results suggest H-ESWT for a high number of sessions is more effective than L-ESWT for a low number of sessions in regard to pain, quality of life, physical function, fatigue, and disability in patients with PF. The short term follow-up (one month) did not allow for assessment of intermediate and long-term outcomes. A small sample size ($n = 94$) makes it difficult to determine whether these conclusions can be generalized to a larger population. Further investigation is needed before clinical usefulness of this procedure is proven.

Xu et al. (2020) conducted a block randomized controlled trial that compared the effect of extracorporeal shock wave therapy (ESWT) and local corticosteroid injection (LCI) on patients with plantar fasciitis (PF). Patients ($n=96$) were randomly assigned to receive ESWT or LCI. Forty nine patients received three low-energy radial ESWT sessions once per week for three consecutive weeks and forty-seven patients received LCI using 40 mg of methylprednisolone and 1 ml of 1% lidocaine. All patients used adjuvant plantar fasciitis therapies, which included passive dorsiflexion of the toes and gastrocnemius stretching twice a day for one month. Additionally, patients were asked to avoid the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and excessive activities during the intervention period. Included patients were age 18 years and older diagnosed with plantar fasciitis more than three months ago, average pain in the last week was > 3 on the visual analog scale (VAS) and plantar fascia thickness (PFT) measured > 4 mm on ultrasound. Follow-up occurred at one, three and six months. Measure outcomes included average pain, first-step pain, plantar fascia thickness, and Foot Function Index, Chinese version of the PF patients. All patients had statistically significant improvement in pain relief and function at each follow-up visit compared with baseline ($p<0.05$). Additionally, significant recovery was maintained at the final visit in the ESWT group, but it was not maintained at three and six months in the LCI group. In both groups, the FFI score showed a significant reduction when compared to baseline, but there was significantly better improvement in the ESWT group than in the LCI group at the three and six month follow-up visits ($p<0.05$). There was a significant improvement in the PFT in both at the three and six month follow-up visits compared to baseline, with significantly better improvement in the ESWT group than in the LCI group at the six-month follow-up ($p<0.05$). The side effects or complications were recorded during treatment and each follow-up visit. All patients exhibited transient reddening of the skin after shock wave therapy, and 13 patients reported transient pain during ESWT, but this pain resolved immediately. No other clinically relevant side effects were observed. Author noted limitations include the short term follow-up and lack of placebo control group. Additionally, it may be more effective to measure PFT using an MRI and different treatment protocols, or shock wave energies may produce different results.

Çağlar Okur and Aydın (2019) conducted a prospective randomized controlled trial (RCT) that investigated the effectiveness of extracorporeal shock wave therapy (ESWT) and custom foot orthotics (CFO) in patients with plantar fasciitis. The patients ($n=83$) were randomized into two groups. Group I ($n=40$) received three sessions of ESWT once a week and group II ($n=43$) received a custom foot orthotic. The study included patients aged 30–60 years diagnosed with plantar fasciitis that experienced persistent heel pain while walking, had pain and sensitivity in the sole and showed abnormal foot pronation due to pain. Patients were assessed in terms of pain at rest, pain during walking (morning and evening), foot functions and foot health using the visual analogue scale (VAS), the Foot Function Index Revised (FFI-R), and the Foot Health Status Questionnaire (FHSQ). The data were obtained prior to treatment (0) and at four, 12, 24 and 48 weeks after treatment. Three patients were lost to follow-up and were excluded from the study data. There were no significant differences in the ESWT and CFO groups between week 0 and week four ($p>0.05$). At post-treatment week 12, the physical activity sub-parameter of FHSQ was

significantly different in favor of the CFO group ($p < 0.05$). At week post-treatment 24, there was a significant difference in evening VAS and FHSQ sub-parameters foot pain, foot function, general foot health and physical activity in favor of the CFO group ($p < 0.05$). At week post-treatment 48, there was a significant difference in evening walking VAS scores; FFI and FHSQ sub-parameters foot pain, foot function and physical activity in favor of the CFO group ($p < 0.001$). Author noted limitations included the lack of a control group, pain was completely resolved and the use of subjective evaluation measures. The authors concluded that ESWT and CFO are both effective modalities but neither method was superior in the treatment of PF.

Mishra et al. (2019) conducted a prospective comparative nonrandomized trial that investigated and compared the effectiveness of methylprednisolone injections (DMP) and extra-corporeal shock wave therapy (ESWT) in treating plantar fasciitis. Patients ($n=60$) were divided into two groups based on the patients' preference. Group 1 ($n=30$) received a methylprednisolone injection at the point of maximal tenderness (PMT) and group 2 ($n=30$) received ESWT. The primary outcome was reduced pain which was measured using the Visual Analogue Pain Scale (VAS). Follow ups of both groups occurred at six weeks, three months and six months. Results at six weeks and six months revealed a significant VAS score improvement with patients in the ESWT group compared to patients of the DMP group ($p=0.005$; $p=0.02$, respectively). Author noted limitations included the small sample size, non-randomized design with possible selection bias, heterogeneous patient population, lack of functional scoring and a short term follow up. The authors concluded that future research with long term follow-up is needed to consolidate the preliminary observations made in this study.

Lai et al. (2018) published the results of a prospective randomized controlled trial which evaluated and compared the therapeutic effects of ESWT and corticosteroid injections (CSI) in patients with chronic plantar fasciitis. The study also examined the correlation between plantar fascia thickness changes and clinical outcomes. Patients were included if they had more than two months without an injection and had been treated with conservative treatment for one month, without improvement before proceeding to ESWT or CSI treatment. Patients ($n=110$) were randomly assigned to receive ESWT ($n=55$) or CSI ($n=55$). The outcomes measured were a decrease in pain over a 12 week period and an increase in plantar fascia thickness. Outcomes were measured before treatment and at the fourth and 12th week following treatment using the visual analog scale (VAS), 100-points scoring system and ultrasound. Thirteen subjects were lost to follow-up and the outcomes were reported on the patients ($n=97$) that completed the study ($n=47$ /ESWT group; $n=50$ /CSI group). The VAS of patients that received ESWT was lower than those who received corticosteroid injection at the fourth and 12th week ($p=0.001$ and $p < 0.001$ respectively). The 100-points scoring system indicated that the pain level of patients with ESWT was significantly lower than those with CSI at the 12th week ($p < 0.001$). The analysis performed comparing changes in plantar fascia thickness to clinical outcomes found that the increase in the thickness of the plantar fascia at the fourth week was positively correlated with the VAS score at 12th week ($p=0.039$) indicating that pain decreased as the plantar fascia thickness increased. At the fourth week, the plantar fascia was thicker in the ESWT group compared to the CSI group ($p=0.048$). However, the thickness decreased in both groups at the 12th week. The author noted limitations of the study included: plantar fascia thickness was not measured on the normal foot, patients lost to follow-up, small patient population, and short term follow-up. The authors summarized that extracorporeal shockwave therapy (ESWT) was more efficient in reducing chronic fasciitis pain after 12 weeks than corticosteroid injection. Furthermore, the increase in plantar fascia thickness after ESWT, the more efficient the clinical outcome. However, further long term studies with large patient populations are needed to validate the findings of this study.

Dedes et al. (2018) conducted a nonrandomized controlled trial to evaluate the effectiveness and safety of shockwave therapy in treating tendinopathies. Patients were excluded if they were under the age of 18. The sample consisted of 384 patients suffering from elbow tendinopathy, plantar

fasciitis, Achilles tendinopathy or rotator cuff tendinopathy. Three hundred and twenty-six patients received shockwave therapy and 58 patients received conservative treatment making up the control group. The purpose of the study was to investigate the pain reduction, the improvement in the patient's functionality and quality of life both immediately and four weeks after therapeutic intervention using anonymous questionnaires. Additionally, comparisons were performed between the shockwave intervention group and control group. The shockwave therapy group in patients suffering from plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy reported significant improvements in all parameters measured post-treatment and at the four-week follow-up ($p < 0.001$). The control group also reported significant improvement post-treatment for each type of tendinopathy ($p < 0.001$). However, in the four week follow-up, the results in the shockwave group were significantly better compared to control group. Significant pain reduction and improvement in functionality and quality of life were observed in both groups of each tendinopathy, but these findings were less pronounced in the control group than those in the shock wave group. Author acknowledged limitation was that direct comparison to other studies was difficult due to the lack of consistent shockwave therapy guidelines. Further research and clinical trials are necessary to clarify the ideal parameters on the efficacy of shockwave therapy.

Sun et al. (2017) performed a meta-analysis of RCTs ($n = 9$ studies/935 subjects) to compare the effectiveness of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) to placebo for chronic plantar fasciitis. RCTs were included that investigated ESWT without anesthesia with sham therapy as control. Therapeutic success in studies was defined as a decrease in visual analogue scale (VAS) score from baseline larger than 50% or 60%, or VAS score of less than 4cm after intervention. Overall, ESWT was found to have higher improvement or success rates than placebo ($p < 0.00001$). A subgroup analysis of FSW and RSW therapies indicated that FSW therapy had greater improvement or success rates than placebo ($p < 0.0001$). Data regarding reduction in pain scale was reported in 4/9 trials. Of these trials, three compared FSW therapy to placebo, and one assessed RSW therapy compared to placebo. Significant heterogeneity was observed in the comparisons of reduction in pain scale. ESWT was found to have greater reduction in pain scale than placebo ($p = 0.05$). No serious adverse events were reported. Limitations of the analysis include the lack of comparison to established treatment methods. The authors concluded that FSW may be associated with higher success rate and greater pain reduction compared to sham therapy in chronic plantar fasciitis patients. However, additional high-quality clinical trials and systemic reviews are needed to demonstrate the efficacy of ESWT (e.g., FSW, RSW therapies) and determine whether RSW therapy is an ideal alternative therapeutic method to conservative treatment and surgery.

A Directory Report published by Hayes reviewed the available literature on focused ESWT for Chronic Plantar Fasciitis. The review included randomized controlled trials (RCTs) ($n = 17$ studies), with studies comparing ESWT to sham treatment (10 RCTs), or to other active treatments (six RCTs), and one RCT comparing full-dose ESWT to low-dose ESWT. Sample sizes ranged from 54–293 patients. Outcome measures in studies were patient-rated pain on visual analog scale (VAS), pain threshold, functional measures, quality of life (QOL), overall treatment success, and complications. Follow-up occurred through five years. Some evidence was found suggesting that ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, however study results were conflicting. Most of the complications reported were transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall body of evidence evaluating ESWT for plantar fasciitis was described as large in size and moderate in quality. The authors noted that despite some positive findings, placebo-controlled trials did not consistently demonstrate statistically significant differences in outcomes between ESWT and sham treatment. It was concluded that additional controlled, blinded long-term safety data from well-designed trials on ESWT for plantar fasciitis are needed further evaluate the technology. Studies identified in a 2019 update of the Hayes Medical Technology Directory report did not change this conclusion (Hayes, 2016a).

Another published Hayes Directory Report reviewed the available literature on radial ESWT for chronic plantar fasciitis. The review included RCTs (n=10 studies), with studies comparing radial ESWT to sham treatment (four RCTs), or to other active treatments (five RCTs), and one RCT comparing radial ESWT with focused ESWT. Sample sizes ranged from 25 to 252 patients. Outcome measures in studies were patient-rated pain on VAS, pain threshold, functional measures, QOL, overall treatment success, and complications. Follow-up ranged from two months to 24 months. Although some of the moderate-size body of evidence suggested that radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, results were conflicting. When reported, complications were primarily transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall quality of the evidence was low with a small amount of long-term safety data available. Limitations of the of evidence includes methodological weaknesses of individual studies such as lack of long-term follow-up, confounding due to secondary treatments, and high loss to follow-up. Similar to the findings with focused ESWT for the treatment of plantar fasciitis, it was concluded that additional controlled, blinded long-term studies are needed to assess the safety and effectiveness of radial ESWT. Studies identified in a 2018 update of the Hayes Medical Technology Directory report did not change this conclusion. Studies identified in a 2019 update of the Hayes Medical Technology Directory report did not change this conclusion (Hayes 2016b).

A 2016 report issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed evidence (n=7 systematic reviews) on the effectiveness of shockwave therapy for pain associated with lower extremity orthopedic disorders. Studies included adults with chronic pain associated with lower extremity orthopedic disorders treated (e.g., plantar fasciitis or heel pain; patellar tendinopathy or knee pain; medial tibial stress syndrome, or shin pain) with shockwave therapy or a comparator. Outcomes in studies were pain reduction, reduced need for opioids, and adverse events. Articles comparing different types of SWT without a non-SWT arm were excluded, as well as studies on fracture, cancer pain, arthritis pain, and back pain. The report concluded that there is some suggestion that SWT is an effective treatment option in comparison to placebo for plantar fasciitis. Limited evidence was found to suggest that the effectiveness of SWT is comparable to platelet rich plasma injection, corticosteroid injection or surgery. Adverse effects reported with SWT included skin reddening, bruising at the site of application, and local swelling and pain. Studies demonstrated inconsistent results for SWT used to treat greater trochanteric pain syndrome, patellar tendinopathy, and medial tibial stress syndrome. It was concluded that more evidence is needed to determine whether SWT is more clinically effective than surgery for pain associated with lower extremity orthopedic disorders (CADTH, 2016).

A number of systematic reviews and meta-analysis (n=6–11 studies/550–1287 patients) have evaluated the effectiveness of ESWT in treating chronic plantar fasciitis. These studies have been limited by short-term follow-up of 3–12 months, and have yielded conflicting results (Xiong, et al., 2019; Li, et al., 2018a; Li, et al., 2018b).

Yin et al. (2014) reviewed low intensity and high intensity ESWT. The authors noted that the pooled data for pain relief in the low-intensity group showed a significant difference between the ESWT and control groups ($p < 0.001$) in favor of ESWT. The high-intensity group was found to have superior pain relief relative to the control group in one trial only. However, with analysis of short-term function, only low-intensity ESWT was significantly superior over the control treatment. Study results in this review indicated that low-intensity ESWT for the treatment of refractory plantar fasciitis may be more effective than sham treatment. Study limitations of heterogeneity and short-term follow-up made it difficult to draw conclusions regarding efficacy. Dizon et al. (2013) review concluded that when ESWT was compared to placebo, ESWT was more effective in reducing morning pain ($p = 0.004$), but no differences were seen in decreasing overall pain or activity pain ($p = 0.06$ and $p = 0.07$ respectively). In a subgroup analysis, moderate-intensity ESWT

was more effective in decreasing overall pain and activity pain ($p < 0.00001$ and $p = 0.001$ respectively). Both moderate- and high-intensity ESWT were more effective in improving functional outcome ($p = 0.0001$). Acknowledged study limitations included the lack of consistency in outcome measures, specified dose intensities (low, medium, high ESWT) and short-term follow-up. Aqil et al. (2013) reported at the 12-week follow-up, patients who received ESWT had better composite pain scores ($p = 0.02$), and greater reduction in their VAS pain scores ($p < 0.001$) compared to placebo. However, there was no significant difference in overall success rate of heel pain improvement between ESWT and placebo ($p = 0.10$). This study also noted limitations which included short-term follow-up and inconsistency of dose intensity.

An RCT ($n = 102$) by Rompe et al. (2010) reported significantly greater changes in the Foot Function Index sum score for patients managed with plantar fascia-specific stretching ($n = 54$) than for those managed with shock-wave therapy ($n = 48$) ($p < 0.001$) two months after baseline.

Numerous studies have investigated the efficacy of ESWT for plantar fasciitis. However, in general, these studies have limitations such as small sample sizes, short-term follow-up, along with variability in results that limit the generalizability of their results. As such, ESWT for this indication remains unproven.

Insoles with Magnetic Foil: The theory behind magnet therapy is that magnetic fields create an electrical current that interrupts the transmission of pain signals in the central nervous system as well as increasing blood flow to an area, boosting the flow of oxygen and other nutrients, ultimately reducing pain and swelling. Two RCTs comparing magnetic versus sham insoles for reducing pain have demonstrated that there is no difference between the therapies in patients with plantar fasciitis (Winemiller, et al., 2003; Caselli, et al., 1997). The limited evidence found in the published peer-reviewed literature does not support the use of magnetic insoles for the treatment of plantar fasciitis.

Intracorporeal Pneumatic Shock Therapy: Intracorporeal pneumatic shock therapy (IPST) using a pneumatic lithotripter has also been proposed for the treatment of chronic plantar fasciitis. Lithotripsy with this device is commonly used to treat kidney and bladder stones.

Literature Review IPST: Few studies exist in the published peer-reviewed medical literature evaluating the safety and effectiveness of IPST for the indication of plantar fasciitis. Dogramaci et al. (2010) conducted an RCT ($n = 50$) in which patients were assigned to treatment with IPST ($n = 25$) or to a placebo group ($n = 25$). At six months of follow-up the rate of successful outcomes (i.e., pain, function) in the treatment group were significantly higher compared to the control group ($p < 0.001$). No complications caused by the procedure were observed during the study. Study limitations include small sample size and short-term follow-up.

There is insufficient evidence in the published peer-reviewed medical literature to support IPST for the treatment of plantar fasciitis.

Laser Therapy: Laser therapy, also called low-level laser therapy (LLLT) is a form of phototherapy which involves the application of low-power monochromatic and coherent light to injuries and lesions to stimulate healing. LLLT is used to increase the speed, quality and tensile strength of tissue repair, resolve inflammation, and give pain relief.

Literature Review Laser Therapy: Cinar et al. (2018) performed a randomized controlled trial (RCT) comparing the efficacy of low-level laser therapy (LLLT) and exercise to orthotic support and exercise (usual care) in the treatment of plantar fasciitis. The patients were randomized into two groups: LLLT ($n = 27$) and control ($n = 22$). The LLLT group received a home exercise program with orthotic support along with gallium-aluminum-arsenide laser with an 850-nm wavelength for

ten sessions, three times a week. The control group received home exercise program with orthotic support. Patients were included per the following criteria: pain located on medial tubercle or along the medial process of the plantar fascia persisting for at least one month with a minimum score of five on the 10-point visual analog scale (VAS), pain felt over the plantar fascia in the morning at first step in the week prior to enrollment, tenderness to palpation over medial calcaneal tuberosity or along plantar fascia, age 18 and older, and agreement to complete treatment and follow-up assessments. Functional outcomes were measured by function subscale of American Orthopedic Foot and Ankle Society Score (AOFAS-F) and 12-min walking test including walking speed, cadence, and activity-related pain using visual analog scale (VAS). The scores were recorded at baseline, third week, and third month after the treatment with three patients being lost to follow-up. There was a significant improvement in AOFAS-F total score at three weeks in both groups (LLLT, $p < 0.001$; control, $p = 0.002$). The groups were comparable with each other for both walking speed and cadence at all assessment times ($p > 0.05$). Both groups showed significant reduction in pain over three months (LLLT, $p < 0.001$; control, $p = 0.01$); however, the LLLT group had lower pain than the control group at three months ($p = 0.03$). Study limitations included: the lack of standardization of the LLLT dose and frequency along with the position of the foot during treatment and the lack of a non-treatment group. The authors concluded that combination therapy of LLLT with usual care is more effective to improve functional outcomes and activity-related pain when compared to usual care alone. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed to support the outcomes of this study.

Ulusoy et al. (2017) reported the results of an RCT ($n = 60$) comparing the effectiveness of low-level laser therapy (LLLT), therapeutic ultrasound (US) therapy, and extracorporeal shock wave therapy (ESWT) using magnetic resonance imaging (MRI). Inclusion criteria were symptoms of a chronic recalcitrant plantar painful heel for six months unresponsive to six weeks of conservative treatment (e.g., nonsteroidal anti-inflammatory drug, home exercise program, and standard insoles). Exclusion criteria included previous local trauma, foot surgery, local steroid injection within the previous three months, diabetes mellitus, and plantar fascial rupture. Patients were randomized into three treatment groups: Group one underwent 15 sessions of LLLT; group two underwent 15 sessions of continuous US; and group three underwent three sessions of ESWT. The primary outcome was defined as a 60% decrease in heel pain for two VAS measurements. Secondary outcome measures were a functional response to treatment and a reduction in plantar fascial thickness on MRI. Data from 54 patients were analyzed for the primary outcome and 52 for the MRI evaluations. At six-week follow up, the VAS score had significantly decreased and the AOFAS scale scores had significantly improved after treatment in all three groups ($p < 0.05$). In the comparison, LLLT and ESWT were found to be more effective than US therapy, with no significant difference found between LLLT and ESWT in the success rate (VAS score 60%). A significant decrease was found in fascia thickness in all three groups after treatment. No statistically significant difference was found between the groups in the reduction of the fascia thickness measured on MRI. Side effects were not observed in any patient. Study limitations include small patient population and short follow-up timeframe. Study results suggest that LLLT and ESWT may be superior to therapeutic US in decreasing pain associated with chronic recalcitrant plantar fasciitis. However additional well-designed studies with sample sizes are needed to draw conclusions on treatment effectiveness for this indication.

Macias et al. (2015) performed a placebo-controlled, randomized, double-blind, multicenter study to evaluate the clinical utility of low-level laser therapy for the treatment of unilateral chronic fasciitis. Patients were included who had a primary complaint of heel pain on weight-bearing after a period of rest; chronic heel pain that persisted three months with no evidence of acute trauma to the heel; average self-rating pain score of 50 using a 100-point visual analog scale (VAS) after taking some initial steps following a period of rest both on the day of study qualification and at baseline; and heel pain that was unresponsive to any conservative form of plantar fasciitis care (i.e., rest, taping, stretching, orthotics, shoe modifications, night splinting, casting, physical

therapy, prescription NSAIDs when taken for a minimum period of two weeks, or local corticosteroid injections). Exclusion criteria included mechanical posterior heel pain categorized as insertional Achilles tendonitis or bursitis; neurologic or arthritic heel pain; type 1 diabetes; sensory neuropathy; or peripheral vascular disease. Participants were treated twice a week for three weeks and were evaluated throughout eight weeks. Pain ratings were recorded using a VAS. At the final follow-up, the treatment group demonstrated a statistically significant improvement ($p < 0.001$) in heel pain compared to the placebo subjects. No adverse events were reported. Study results are limited by small sample size and short-term follow-up period.

In a randomized, double-blind, placebo-controlled trial ($n=25$), Kiritsi et al. (2009) compared the effect of low-level laser therapy (LLLT) ($n=15$) versus placebo ($n=10$) on plantar fasciitis. Outcomes were documented by ultrasound of the plantar fascia and reported pain scores. Enrolled patients had unilateral plantar fasciitis, so the contralateral asymptomatic fascia was used as control. Pain levels were reported to be significantly improved after LLLT compared to the placebo group (i.e., after night rest [$p=0.006$], with daily activities [$p=0.01$]). The small sample size of this study limits the generalizability of results.

The available data regarding the efficacy of laser therapy for the treatment of plantar fasciitis is limited.

Low-Load Prolonged-Duration Stretch (LLPS) Devices: LLPS also referred to as dynamic splinting uses a prolonged duration stretch with calibrated, adjustable tension to increase time at end range of motion and thereby reducing contracture. Stretching with dynamic splinting has been proposed as a treatment for plantar fasciitis because the tension can adapt to changes in the plantar fascia. Available LLPS/dynamic splinting devices include:

- Dynasplint System® (Dynasplint Systems, Inc., Severna Park, MD)
- Ultraflex (Ultraflex Systems, Pottstown, PA)
- Pro-glide™ Dynamic ROM devices (DeRoyal®, Powell, TN)
- Advance Dynamic ROM® devices (Empi, St. Paul, MN)

Literature Review LLPS: Studies in the published peer-reviewed medical literature evaluating the safety and effectiveness of include an RCT ($n=60$) by Sheridan et al. (2010). All patients received nonsteroidal anti-inflammatory drugs, orthoses, and corticosteroid injections as needed. The experimental group ($n=30$) also received dynamic splinting worn at night to obtain a LLPS with dynamic tension. A significant difference was found in the mean change from baseline in Plantar Fasciopathy Pain/Disability Scale scores of experimental over control patients ($p < 0.0001$).

Although the results of one RCT suggest that dynamic splinting may be effective in reducing the pain of plantar fasciopathy, additional well-designed randomized controlled clinical trials with adequate patient populations and follow-up are needed to support the safety and efficacy of this intervention. There is insufficient evidence in the published peer-reviewed literature to support the use of LLPS /dynamic splinting for plantar fasciitis.

Microwave Diathermy: Microwave diathermy uses microwave radiation to create heat within the tissues. There is no evidence supporting the efficacy of this modality in the treatment of plantar fasciitis (Crawford and Thomson, 2003).

Percutaneous Ultrasonic Ablation: Percutaneous ultrasonic ablation is also being investigated as a treatment for refractory plantar fasciitis. Ultrasonic ablation devices break up degenerative soft tissue via ultrasound guidance so that the damaged tissue can be aspirated or removed. The Tenex Health TX System® (Tenex Health, Inc., Lake Forest, CA) was granted marketing approval by the FDA via the 510(k) process on March 3, 2016, because it is considered to be substantially

equivalent to another device already on the market. The 510(k) summary stated that the system is substantially equivalent to the TX1 Tissue Removal System. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness prior to marketing the device. The system consists of a console that houses user functions (e.g., irrigation and aspiration pumps), ultrasonic hand piece, inflation cuff, and foot pedal which controls the device functions. The FDA states that the Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgery (FDA, 2016).

Literature Review Percutaneous Ultrasonic Ablation: There is a paucity of studies investigating the safety and efficacy of ultrasonic ablation for plantar fasciitis consisting of few case series with small patient populations (Sanchez, et al., 2017).

In 2020 Hayes, Inc. published an evidence analysis research brief evaluating the use of percutaneous ultrasonic tenotomy using the Tenex System (Tenex Health) for the treatment of plantar fasciitis. The review included six abstracts, including one case report (n=1), four reviews/commentaries and one prospective comparative study. It is noted that one case report and one prospective cohort study, may have used a device other than Tenex. Hayes concluded that there is insufficient published evidence to assess the safety and/or impact of the Tenex Health Tx percutaneous ultrasound ablation system on health outcomes or patient management of plantar fasciitis in adults. (Hayes, 2020).

Based on the lack of published data, the procedure is considered unproven for the treatment of chronic plantar fasciitis.

Pulsed Radiofrequency Electromagnetic Field (PREF) Therapy: Pulsed radiofrequency electromagnetic field (PREF) is noninvasive modality that delivers electromagnetic energy into soft tissue, generating an electric field that is thought to facilitate a therapeutic effect. The exact mechanism by which PREF interacts with cells to initiate a therapeutic effect is not fully understood (Rawe, 2012). PREF has been investigated for indications such as postoperative pain control, wound healing, soft tissue injury and more recently for treatment of plantar fasciitis therapy.

Literature Review PREF: There is paucity of evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of PREF for plantar fasciitis. A double-blind, multicenter, randomized, placebo-controlled study (n=70) was used to evaluate a small, wearable, extended-use PREF device worn overnight. The primary outcome measure was morning pain. A significantly different decline was reported between the study and control groups (p=0.03). Although the results of this small study are positive, there is currently insufficient evidence demonstrating safety and efficacy of PREF for the indication of plantar fasciitis (Brook, et al., 2012).

Radiotherapy: Radiotherapy for plantar fasciitis treatment has been well-established in Germany for many years. The exact radiobiological mechanisms of the effect of ionizing radiation on plantar fasciitis have not been completely investigated and understood.

Literature Review Radiotherapy: Canyilmaz et al. (2015) conducted an RCT (n=128 patients) comparing radiation therapy (n=64) to local steroid injections (n=64) for plantar fasciitis. Patients aged 40 or older were included if they had symptoms longer than six months and a clinical diagnosis of a painful heel spur. Patients who had previous radiation therapy, trauma to the foot, severe psychiatric disorders, rheumatic and/or vascular diseases, or were pregnant or breastfeeding were excluded from the study. The primary endpoint was pain reduction measured

by several pain scales including the visual analog scale (VAS). The median follow-up period for all patients was 12.5 months (range, 6.5-18.6 months). At six-month follow-up, the mean differences in VAS scores after treatment compared with the values before radiation therapy was 2.7 in the radiation therapy arm and 4.6 in the steroid injection group. There was a statistically significant difference in favor of radiation therapy ($p < 0.001$). Results in the short-term indicate that radiation therapy has a greater analgesic effect on pain from plantar fasciitis than steroid injections. However long-term study results are needed to support this finding.

An RCT ($n=66$) by Niewald et al. (2012) assigned patients with painful heel spur/plantar fasciitis to receive a standard dose versus a low dose of radiation therapy. Follow-up continued through one year. After three months the results in the standard arm measured by visual analogue scale were significantly improved compared to those in the low-dose arm ($p=0.001$). At 12 months follow-up significant fewer patients were re-irradiated in the standard arm compared with the low-dose arm ($p < 0.001$). Patients who had a favorable result after three months showed this even after 12 months.

Further research is needed to demonstrate the safety and efficacy of radiotherapy for the treatment of plantar fasciitis.

Stem Cell Therapy: Stem cell therapy refers to mesenchymal stem cells harvested from bone marrow, adipose tissue, amniotic membrane, peripheral blood and/or synovial tissue. Stem cells are cells that have the ability to differentiate into a number of various cell types and are being used more frequently in the treatment of orthopedic and/or musculoskeletal conditions. There are various types of stem cells which include but are not limited to embryonic, mesenchymal, and hematopoietic. Embryonic stem cells are isolated from embryonic tissue, while both mesenchymal and hematopoietic are isolated using adult bone marrow. While some stem cells are restricted to a few lineages, others may differentiate into a wide variety of cell types. Hematopoietic stem cell transplantation is the only stem cell therapy well-established in clinical practice (Gepstein and Skorecki, 2020).

Within orthopedics, mesenchymal stem cells are derived mainly from bone marrow, however other sources include adipose tissue (i.e., lipoaspirate), umbilical cord tissue, amniotic fluid, and other extra-articular sources. Mesenchymal stem cells (MSCs) are adult-derived, undifferentiated, multipotent cells that express a variety of different cell surface proteins and can differentiate into a variety of lineages, such as adipogenic (fat cells), osteogenic (bone cells), and chondrogenic (cartilage cells). Adult MSCs do not reach pluripotency, pluripotency is the ability to differentiate into all cell types derived from three germ layers (i.e., ectoderm, mesoderm, endoderm) of the developing embryo (e.g., embryonic stem cell). If MSCs are placed within normal healthy bone, cartilage, or adipose tissue, the stem cells differentiate into that particular tissue. In theory, this property applies to all mesenchymal tissues, including muscle, tendon, and fibrous tissues. MSCs demonstrate little to no ability however to differentiate into nonmesenchymal tissue (e.g., neural or hepatic cells) (Cook and Young, 2022).

U.S. Food and Drug Administration (FDA): Medical and surgical procedures do not require FDA approval. In addition, the use of concentrated, autologous mesenchymal stem cells (MSCs) do not require FDA approval. The FDA does regulate human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Currently there are no allogenic MSC materials using engineered or expanded MSCs approved by the FDA for orthopaedic applications (Cook and Young, 2022). According to the FDA, "the only stem cell-based products that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood." Safety concerns of the FDA regarding the use of unproven stem cells include administration site reactions, failure of cells to work as expected, the

growth of tumors, and the ability of cells to move from placement sites and change into inappropriate cell types and multiply (FDA, 2020b).

Literature Review Stem Cell Therapy: Areas undergoing current investigation for the application of MSCs include but are not limited to regeneration and/or repair of musculoskeletal tissue, for example muscle, tendon, and fibrous tissues. There is a lack of evidence supporting the efficacy of this modality in the treatment of plantar fasciitis. Therefore, the procedure is considered unproven for the treatment of plantar fasciitis.

Stereotactic Radiofrequency Thermal Lesioning: Stereotactic radiofrequency thermal lesioning, or radiofrequency lesioning, is a minimally invasive procedure, in which a probe the size of a needle is placed through the skin in the heel in the area of pain. While the patient is under intravenous (IV) sedation, the tip of the probe heats up to 87° Celsius (189° Fahrenheit) and is kept there for 90 seconds. The proposed mechanism of action is desensitization of the nerve endings. In a retrospective study of 39 patients, Sollitto et al. (1997) found that 92% of patients experience resolution of symptoms. This study is limited by the lack of a control group and randomization; a more rigorous design is needed.

Trigger-Point Needling and Infiltration: Trigger-point needling for plantar fasciitis is the needling and infiltration of anesthetic into the myofascial trigger points at the proximal portion of the medial gastrocnemius muscle.

Literature Review Trigger-Point Needling and Infiltration: Uygur et al. (2019) conducted a randomized controlled trial to evaluate if dry needling would be as effective as the use of corticosteroid injections for treating plantar fasciitis. Patients (n=98) were randomized to receive dry needling (n=49) twice a week for five sessions or a single steroid injection (n=49). The study included patients aged 18–80 with pain at the plantar medial aspect of the heel for > 3 months, maximal tenderness on clinical examination over the medial tubercle of the calcaneus, pain with palpation of the proximal insertion of the plantar fascia, pain when first stepping onto the heel, and no previous other form of treatment (e.g., insoles, pain medication) during the needling process. Pain, disability, and activity limitation were measured using the foot function index (FFI) with follow-up occurring in the third week and sixth month. Two patients were lost to follow-up and six were unable to give a last control visit. The missing data at the last control was handled by the carrying forward of the last observation (LOCF) method. The outcomes were reported on 49 patients in the dry needling group and 47 in the corticosteroid group. Significant differences between the two groups were detected at both three weeks and six months. In terms of all subscales, the corticosteroid injection group showed a loss of efficacy between the third week and sixth months, which was significant ($p < 0.001$). However, in the dry needling group, there were no significant differences in results between the third week and sixth month. Additionally, the outcomes of dry needling were significantly better at six months ($p < 0.001$) when compared to the corticosteroid group. Adverse effects of dry needling were pain (38%) at the needling site and subcutaneous bleeding (12%) which did not lead to termination of the procedure. No complications occurred in the corticosteroid group during the trial. Author noted limitations included comparing a single-dose corticosteroid application to multiple dry needling applications and using the last observation carry forward method which may have introduced bias.

Dunning et al. (2018) conducted a single-blinded, multi-center randomized clinical trial to compare the effects of adding electrical dry needling into a program of manual therapy, exercise and ultrasound on pain, function and related-disability in individuals with plantar fasciitis (PF). Patients (n=111) with plantar fasciitis were randomized to receive electrical dry needling, manual therapy, exercise and ultrasound (n=58) or manual therapy, exercise and ultrasound (n=53). Patients were included in the study if they were age ≥ 18 years with a clinical diagnosis of PF, plantar heel pain for longer than three months and first-step pain in the morning during the

previous week rated at least two on the numeric pain rating scale. The primary outcome was first-step pain in the morning as measured by the Numeric Pain Rating Scale (NPRS). Secondary outcomes included resting foot pain (NPRS), pain during activity (NPRS), the Lower Extremity Functional Scale (LEFS), the Foot Functional Index (FFI), medication intake, and the Global Rating of Change (GROC). The treatment period was four weeks with follow-up assessments at one week, four weeks, and three months after the first treatment session. Both groups received six sessions of impairment-based manual therapy directed to the lower limb, self-stretching of the plantar fascia and the Achilles tendon, strengthening exercises for the intrinsic muscles of the foot, and therapeutic ultrasound. In addition, the dry needling group also received six sessions of electrical dry needling using a standardized eight point protocol for 20 minutes. All patients completed the study. Patients who received electrical dry needling, manual therapy, exercise and ultrasound experienced significantly greater improvements in first-step morning pain ($p < 0.001$), resting foot pain ($p < 0.001$), pain during activity ($p = 0.007$), LEFS ($p < 0.001$), FFI Pain Subscale ($p < 0.001$), FFI Disability Subscale ($p = 0.004$), and FFI Total Score ($p < 0.001$) than those who received manual therapy, exercise and ultrasound at three months. No differences in FFI Activity Limitation Subscale ($p = 0.104$) were observed. Significantly ($p = 0.023$) more patients in the electrical dry needling group completely stopped taking medication for their pain compared to the manual therapy, exercise and ultrasound group at three months. It was noted that limitations included the lack of long-term follow-up and uncertainty about the results being generalizable to other dry needling protocols, dosages, techniques or needle placements. Additionally, there was the lack of a placebo control group and therapist, and patient treatment preferences were not collected and could potentially affect the results. The authors concluded that the inclusion of electrical dry needling into a program of manual therapy, exercise and ultrasound was more effective for improving pain, function and related-disability than the application of manual therapy, exercise and ultrasound alone in individuals with PF at mid-term. However, additional studies should examine the effectiveness of different types and dosages of electrical dry needling and include a long-term follow-up.

Rastegar et al. (2018) performed a single blind randomized controlled trial (RCT) comparing the efficacy of dry-needling to steroid injection in the treatment of plantar fasciitis. The patients were randomized into two groups: steroid group ($n = 34$) and dry needling group ($n = 32$). The steroid group received an injection containing 1 ml (40 mg/ml) of methylprednisolone acetate into the intended site. The dry-needling group received dry needling using a 0.30-mm needle that was gradually withdrawn and advanced for 30 seconds in the same location as the steroid group. Eligible patients were individuals over age 18 with a three month history of plantar heel pain and diagnosed with plantar fasciitis. The primary outcome measured was plantar pain intensity on the visual analogue scale (VAS) before treatment and at each follow-up. Patients were assessed before treatment, at three weeks, six weeks, three months, six months and one year following treatment. At the three week follow-up, the VAS score was clinically significant in favor of the steroid group ($p < 0.001$). At the six month and one year follow-up, the VAS scores were clinically significant in favor of the dry-needling group ($p < 0.001$, $p = 0.004$), respectively. There were no significant differences between groups at the other time points. The results suggested that steroid injections quickly reduced pain, but after six weeks of treatment the pain increased. In the dry-needling group, pain reduced slowly, but after six weeks of treatment, pain continued to decline. At the end of the study, average pain in the steroid group was greater than in the dry-needling group. The author noted limitations of the study included: the medial plantar region injection point was used as the location for steroid injection and dry needling (where most pain had been focused on) and the needles were not guided using imaging techniques. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed.

He et al. (2017) performed a meta-analysis ($n = 7$ RCTs/417 patients) to evaluate the effect of dry needling of myofascial trigger points (MTrPs) in patients with plantar heel pain. The number of participants in studies ranged from 20–108. Subjects were adults diagnosed with planter heel pain

(plantar fasciitis), with interventions of dry needling/acupuncture of the MTrPs compared to placebo or other treatment as control. Outcome measures included visual analog scale (VAS) score, success rate for pain, and adverse events. Success for pain was defined as a minimum decrease of 50% in VAS scores. Follow up occurred through 12 months. Pooled results showed that MTrP needling significantly reduced the VAS score ($p < 0.001$) compared to control. No significant differences were found between the two interventions in terms of success rate for pain and the incidence of adverse events which were transient. Acknowledged limitations of the analysis include the small sample sizes and substantial heterogeneity of studies. Larger well-designed RCTs are needed to support safety and efficacy of MTrP needling for plantar fasciitis.

Cotchett et al. (2014) published their results of a parallel-group, participant-blinded RCT ($n=84$ patients) of patients with plantar heel pain for at least one month. The mean duration of plantar heel pain was 13.6 months. Subjects were assigned to receive real or sham trigger point dry needling. The treatment consisted of one treatment per week for six weeks. The follow-up period was 12 weeks. Primary outcomes included first-step pain measured with a visual analog scale (VAS), and general foot pain. The secondary outcome measures included foot function and general foot health. The primary end point for predicting the effectiveness of dry needling for plantar heel pain was six weeks. A total of 81 subjects (96.4%) completed the six-week follow-up, and 79 subjects (94.0%) completed follow-up at 12 weeks. At six weeks of follow-up, both groups showed decreased pain but there were significant between-group effects that favored real dry needling over sham dry needling. At six and 12 weeks, there were no significant differences in health-related quality of life between groups. The most common delayed adverse event was bruising, followed by an exacerbation of symptoms. These results suggest that dry needling is more effective than sham for first-step plantar heel pain. However the study results are limited by the single-blind design, relatively small sample size, and short-term follow-up which preclude generalizability.

Cotchett et al. (2010) conducted a systematic review to evaluate the evidence for the effectiveness of dry needling and/or injections alone or in combination with acupuncture. Outcome measures of pain and function were assessed. A total of three quasi-experimental trials ($n=53$ patients) matched the inclusion criteria: two trials found a reduction in pain for the use of trigger point dry needling when combined with acupuncture and the third found a reduction in pain using 1% lidocaine injections when combined with physical therapy. The methodological quality of the three trials was found to be poor. A meta-analysis was not conducted because substantial heterogeneity was present between trials.

Professional Societies/Organizations

American Academy of Orthopaedic Surgeons (AAOS): The AAOS does not take a position for or against the use of stem cell therapy for orthopaedic applications, however within a position statement regarding the use of emerging biologic therapies (AAOS, 2020) the AAOS stated the following: "Surgeons must be aware of the scientific basis for the different treatment options offered to their patients, including benefits and risks. Not all biologic products require extensive FDA regulation, and in some cases, the FDA has primarily focused on safety concerns and has ceded responsibility for determining the efficacy of these products to the clinician."

"The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons should be cognizant of the risks, benefit, regulatory status and labeled indications of the products they use. "For all products, but particularly those which the FDA does not critically evaluate effectiveness data, clinicians bear a greater responsibility to independently weigh that evidence. This responsibility also extends to off-label use of FDA-regulated products, and cases where the devices used to create or deliver the biologic product, rather than the product itself, are what has been approved by the FDA." The statement concluded that "the clinicians using these biologic

products need to be particularly careful to weigh the available evidence and conduct shared decision-making with the patient in the informed consent process.” (AAOS, 2020).

American College of Foot and Ankle Surgeons (ACFAS): According to a consensus statement on the diagnosis and treatment of adult acquired infracalcaneal heel pain, extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis. The ACFAS stated that “since ESWT has few negative consequences and the recovery time is short, with patients typically walking and returning to full activities within a few days, the panel thought that ESWT is a valuable option for providers treating heel pain.” This recommendation was made using systematic reviews with meta-analysis of randomized controlled trials. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed to support the outcomes of the mentioned studies (Schneider, et al., 2018).

The panel also determined that injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) or other surgical techniques (e.g., ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) were uncertain, neither appropriate nor inappropriate (Schneider, et al., 2018).

International Society of Stem Cell Research (ISSCR): The ISSCR published information regarding stem cell types and uses (ISSCR, 2021) and asserts there is little evidence they are beneficial. Mesenchymal stem cell (MSC) therapy remains in early experimental stages. According to ISSCR, MSC are cells that originate from stroma, the connective tissue surrounding tissues and organs. Although various MSCs are thought to have stem cell and immunomodulatory properties as treatment for various disorders. Scientists do not fully understand whether these cells are actually stem cells or what types of cells they are capable of generating. They do agree that not all MSCs are the same, and that their characteristics depend on where in the body they come from and how they are isolated and grown. Some types of stem cells are capable of migration after transplantation, meaning there is a risk of off-target effects and inappropriate integration.

Washington State Health Care Authority (WSHCA): In 2017 the WSHCA conducted a technology assessment that evaluated the comparative efficacy, effectiveness, and safety of ESWT in adults for the treatment of various musculoskeletal and orthopedic conditions, including but not limited to plantar fasciitis, tendinopathies, adhesive capsulitis of the shoulder, and subacromial shoulder pain. As part of the technology assessment a total of 72 randomized controlled trials were included and reviewed. Limitations of the studies noted by the Committee generally included potential for risk bias, short-term follow-up, inconsistency of measured outcomes, and lack of high quality evidence and small sample sizes. The authors concluded extracorporeal shock wave therapy was unproven for efficacy and cost-effectiveness.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Coverage Determination found	
LCD	Novitas Solutions, Inc.	Platelet Rich Plasma L39068	12/12/2021
LCD	CGS Administrators, LLC	Platelet Rich Plasma Injections for Non-Wound Injections L39023	2/9/2023
LCD	National Government Services, Inc	Platelet Rich Plasma L38937	2/10/2022

	Contractor	Determination Name/Number	Revision Effective Date
LCD	Noridian Healthcare Solutions, LLC	Platelet Rich Plasma Injections for Non-Wound Injections L39058	2/15/2023
LCD	Noridian Healthcare Solutions, LLC	Platelet Rich Plasma Injections for Non-Wound Injections L39060	2/15/2023
LCD	Palmetto GBA	Platelet Rich Plasma L38745	3/17/2023
LCD	First Coast Service Options, Inc.	Platelet Rich Plasma L39071	12/12/2021

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Not Covered or Reimbursable when used to report any of the above therapies for the treatment of plantar fasciitis:

CPT®* Codes	Description
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
28899	Unlisted procedure, foot or toes
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day,
97139	Unlisted therapeutic procedure (specify)
97799	Unlisted physical medicine/rehabilitation service or procedure
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

HCPCS Codes	Description
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser, each 15 minutes

Considered Experimental/Investigational/Unproven when used to report any of the above therapies for treatment of plantar fasciitis:

CPT®* Codes	Description
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection(s); single or multiple trigger point(s), 3 or more muscle(s)
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles
28899	Unlisted procedure, foot or toes
97024	Application of a modality to 1 or more areas; diathermy (eg, microwave)
97139	Unlisted therapeutic procedure (specify)
97799	Unlisted physical medicine/rehabilitation service or procedure
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

HCPCS Codes	Description
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1816	Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
Q4100	Skin substitute, not otherwise specified
Q4139	AmnioMatrix, injectable, 1 cc
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4192	Restorigin, 1 cc
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<ul style="list-style-type: none">• No policy statement changes.	2/15/2024

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